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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/551,977	04/14/2000	John M. Polo	930049.489/1593.004	2230

7590 06/04/2002

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EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/04/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/551,977

Applicant(s)

POLO ET AL.

Examiner

Bao Qun Li

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-16, 18 and 24-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17 and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to the Amendment

This is a response to the amendment, paper No. 16, filed 03/20/02. Claim 17 is amended. Claims 1-37 are pending before the examiner.

This application contains claims 1-16, 18, 24-37 drawn to an invention non-elected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01

Please note any ground of rejection that has not been repeated is removed.

The text of those sections of Title 35, US Code not included in this section can be found in a prior office action.

Claim objection

The amendment filed on paper No.16, 03/20, 2002 is objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure as follows: "said recombinant alphavirus particle comprising one or more amino acid mutations in the E1 or E2 polypeptide as compared to wild-type," which is cited in amended claim 17.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections – 35 USC § 112 second paragraph

Applicant's arguments with respect to claim 17 have been considered but are moot in the view of the new ground(s) of rejection.

Claim Rejections – 35 USC § 112 first paragraphs

Claims 17 and 21-23 are still rejected under 35 U.S.C. § 112, first paragraph, on the similar ground as described in the previous Office Action because the specification, while being enabling for having a recombinant Sidbis virus with a mutation at the amino acid residue 160 (Gly to Glu substitution), wherein the said virus is able to infect the

dendritic cell (DC), does not reasonably provide enablement for having any or all recombinant alphavirus particle with one or more mutations at any region being able to infect the DC. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants argue that the instant Applicant is entitled for a claimed genus of any or all alphavirus because of the teachings of the specification readily enable one of skill in the art would not have trouble to select and identify mutations in the alphavirus genome that confer human dendritic cell tropic phenotype and incorporate said mutation into recombinant alphavirus particles. Applicants further assert that the examiner does not establish that it would require undue experimentation for a skilled artisan to make and use the claimed invention because of prior art does not establish the unpredictability.

Applicants' argument is fully considered. However, it is not found persuasive because some mutations of an alphavirus render the virus to become more neurovirulent as evidenced by Tucher et al. cited in the previous office action or a mutation may abolish the ability of an alphavirus to infect the dendritic cell as evidenced by McDonald et al. cited in the previous office action.

Applicants are reminded that alphavirus is an RNA virus, which is susceptible to have a frequent mutation. Some of the mutation may cause severe problems in a host as evidenced by Tucher et al.

Moreover, the specification does not teach that an alphavirus having any other mutation rather than the substitution of an amino acid Gly at position 160 of E2 region with Glu is able to infect dendritic cells.

Therefore, without adequate teaching and guidance, a undue experimentation would be required for a skilled artisan to make a undue experimentation for testing every amino acid in the alphavirus genome, or at least in the region of E1 and E2 in order to figure out which amino acid mutation is proper and enable the full scope of the claimed invention without any expected success.

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New grounds of rejections:

Claim Rejections-35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112.

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. § 112, first paragraph, as containing a new subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification was silent as to mutation in E1 region of an alphavirus. According to page 5, lines 4-9 of the instant application, the disclosure is directed to the mutation in E2 region, for example, at 159, 159, 160, 161, and 162. Within preferred embodiments, the amino acid substitution is at residue 160 of E2. The specification does not have any disclosure about a mutation located in the E1 region that is suitable for changing the cell tropism.

Claim Rejections-35 USC § 112

Claim 17 and 19-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is unclear which amino acid in E1/E2 region is mutated. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Genus*, 988 F.2d 1181, 26USPQ2d 1057 (Fed. Cir. 1993). Because there are many amino acids in the E1 or E2 region, the claim should point out which amino acid is intended. This affects the dependent claims 19-23.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07 (a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

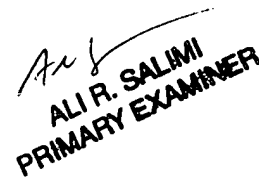
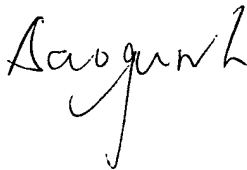
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached from 8:00 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li
May 17, 2002



ALI R. SALIMI
PRIMARY EXAMINER